

SITUATION UPDATE, 10:00 A.M. EST

1. National Smallpox Vaccine Stockpiles

Table 1 compiles the most recent information provided by each country; some countries were reluctant to disclose vaccine stockpile data. The total global inventory of smallpox vaccine is just over 700 million doses, which is enough to vaccinate a little more than 10% of the world's population:

- 40 countries have some smallpox vaccine supply.
- Many countries have little or no vaccine.
- · Some countries have enough vaccine to cover their entire population
- No country has extra vaccine.

Table 1: National Smallpox Vaccine Stockpiles

Nation (* Summit Countries)	# doses (millions)	% population covered	Nation (* Summit Countrie		% population covered
United States*	300	100	Ireland	<1	15
Germany*	100	100	Norway	<1	15
United Kingdom*	80	100	Italy*	5	10
France*	60	100	Belgium	1	10
Netherlands*	20	100	Hungary	1	10
Czech Republic	10	100	Sweden*	1	10
Israel	7	100	Iran	2	5
Denmark	6	100	Australia	<1	5
Singapore	4	100	Poland*	<1	5
South Africa	30	70	India	6	1
Malaysia	15	65	Croatia	<1	1
Austria	3	40	Slovakia	<1	1
Switzerland	3	40	Turkey	<1	1
Japan	31	25	WHO*	2.5	N/A
Korea (Rep. of)	10	20	Total app	proximately 720 million	10%
Canada*	6	20	[†] Obtained from open sources; accurate on 1/14/05; has not been updated.		
Greece	2	20			
Spain	6	15			

2. Methods Used to Determine National Smallpox Vaccine Stockpiles

Vaccine stocks for countries were determined in the following manner: First, a search of open source literature was performed by the *Atlantic Storm* team to determine current country stockpiles. Members of the *Atlantic Storm* team then communicated with officials from the World Health Organization, commercial sources, and other knowledgeable experts to assess the status of global national vaccine stocks.

- Population figures were gathered from the CIA World Factbook. Available at http://www.cia.gov/cia/ publications/factbook/index.html. Accessed December 2004.
- Countries that specifically stated they had sufficient vaccine supplies to vaccinate their populations were assumed to have a number of vaccine doses equal to or greater than their country's population.
- Reports of vaccine orders were assumed to be filled unless there was specific information to the contrary.
- For this exercise, we assumed that nations have sufficient bifurcated needles to administer vaccine, regardless of how much the vaccine was diluted.

3. Smallpox Vaccine Production Capacity

Table 2 summarizes currently available information about the world's annual smallpox vaccine production capacity. Smallpox vaccine must be made in dedicated facilities, and other vaccine production facilities cannot be easily converted to make smallpox vaccine.

• Four companies make smallpox vaccine.

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- Total global production capacity is 274 million doses per year, or 23 million doses per month.
- Under emergency conditions, production could be ramped up to produce 480 million doses per year. Even with ramped up production capacity, it would take 10 years to produce enough vaccine for the entire planet.
- Russia is thought to have production capacity of 25 million doses per year, but this data is not yet confirmed.

Table 2: Smallpox Vaccine Production Capacity

Company	Country of Production [†]	Production Capacity (million doses/year)	Production Capacity (million doses/month)
Acambis/Baxter	United States/Austria	100	8.3
Bavarian-Nordic	Denmark/Germany	150	12.5
RIVM	Netherlands	2-4	0.16-0.30
Kaketsuken	Japan	10-20	0.83-1.6
Total Production (combined)		274	22.8
Total Emergency I	Production (combined)	480	40

Obtained from open sources; accurate on 1/14/05; has not been updated.

[†]Russian capacity unknown: ~ 25M doses/yr ??

4. Smallpox Vaccine Dilution

Several U.S. studies¹ have suggested that the U.S. vaccine can be safely diluted 5-to-1, and health officials have stated publicly that in the event of a crisis, the U.S. could dilute its vaccine supply. This type of dilution has never been used in an actual emergency.

- The European Commission² has reviewed the two U.S. dilution studies and concluded that diluting vaccine would be inadvisable. The EC believes that dilution would increase the risk of ineffective inoculations.
- WHO has decided that there will be no diluted vaccine in the WHO stockpile because of the risks associated with dilution.

5. National Smallpox Vaccination Strategies

- Rationale for Ring Vaccination: Ring (targeted) vaccination is the preferred strategy for all countries, and is the strategy advised by the WHO. Targeted vaccination will ensure that vaccine is used where it is most needed. If countries use targeted vaccination, there will be more vaccine available to share with other nations.
- Rationale for Mass Vaccination: Mass vaccination will provide immediate protection for all persons who are vaccinated. Mass vaccination will protect against future or ongoing smallpox attacks. Political pressure and public demand for mass vaccination will be extreme.
- Mass vaccination will be difficult because there is no existing international framework to plan or implement vaccine sharing between nations. Many nations do not have enough vaccine for all of their citizens. No nations have implemented such a mass vaccination campaign in decades.

6. International Vaccine Sharing

- Summit participants must decide whether or not to share national vaccine supplies. Vaccine can be shared through bilateral and/or multilateral arrangements.
- There are no existing multilateral arrangements for international vaccine sharing. The WHO, NATO, the EU, the UN, or an ad hoc sharing coalition are all international entities that might be used to share national vaccine stockpiles. While some of these entities have worked on developing virtual stockpiles that could be used in a crisis, none have been used in an actual crisis situation. Also, it is important to note the EU explicitly decided not to have a smallpox vaccine stockpile because of the challenge of implementing a stockpile during a crisis.



1 Studies and News Reports on Dilution of U.S. Smallpox Vaccine

Frey SE, Couch RB, Tacket CO, Treanor JJ, Wolff M, Newman FK, Atmar RL, Edelman R, Nolan CM, Belshe RB, the National Institute of Allergy and Infectious Diseases Smallpox Vaccine Study Group, Clinical responses to undiluted and diluted smallpox vaccine. N Engl J Med 2002 346:1265-1274. Available at: http://content.nejm.org/cgi/content/ full/346/17/1265. Accessed January 2005.

- Talbot TR, Stapleton JT, Brady RC, Winokur PL, Bernstein DI, Germanson T, Yoder SM, Rock MT, Crowe JE Jr, Edwards KM. Vaccination success rate and reaction profile with diluted and undiluted smallpox vaccine: a randomized controlled trial. JAMA 2004 292:1205-1212. Available at: http://jama.ama-assn.org/cgi/content/full/292/10/1205. Accessed January 2005.
- National Institutes of Health, National Institute for Allergy and Infectious Diseases. Press release: NIAID study results support diluting smallpox vaccine stockpile to stretch supply. 2002 March 28. Available at: http://www2.niaid.nih.gov/newsroom/ releases/smallpox.htm. Accessed January 2005.
- Roos R. NIAID study: diluted smallpox vaccine remains potent. CIDRAP News Report. 2002 March 29. Available at: http:// www.cidrap.umn.edu/cidrap/content/bt/smallpox/news/vacdilution.html. Accessed January 2005.

2 European Commission Position on Smallpox Vaccine Dilution

Gouvras G. Policies in place throughout the world: action by the European Union. *Int J Infect Dis.* 2004 Oct;8 Suppl 2:S21-30. Available at: http://dx.doi.org/10.1016/j.ijid.2004.09.003. Accessed January 2005.